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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,847	07/24/2003	Bertrand Pain	37991-0017	8939
26633 7590 08/08/2008 HEILER EHRMAN LLP 4350 La Jolla Village Drive, 7th Floor San Diego, CA 92122				
EXAMINER KAUSHAL, SUMESH				
ART UNIT		PAPER NUMBER		
1633				
MAIL DATE		DELIVERY MODE		
08/08/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/625,847

Applicant(s)

PAIN ET AL.

Examiner

Sumesh Kaushal

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 58, 61, 66, 68, 69, 71 and 73-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58, 61, 66, 68, 69, 71 and 73-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ ~~Notice of Informal Patent Application~~
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's response and Guehenneux's and Mehtali's declaration filed on 04/30/08 has been acknowledged and fully considered.

Claims 58, 61, 66, 68-69, 71 and 73-76 are pending and are examined in this office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 58, 61, 66, 68-69, 71 and 73-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reason of record as set forth in the office action mailed on 10/30/07.

RESPONSE TO ARGUMENT (ENABLEMENT)

In view of Guehenneux's and Mehtali's declaration filed on 04/30/08, the applicant argues that applicants have shown that the present methods can be used to produce non adherent chicken embryonic stem cell lines capable of proliferating in a basal medium in the absence of exogenous trophic factors and cytokines. However the applicant's arguments are found not fully persuasive because at best the Guehenneux's and Mehtali's declaration demonstrated the making of a cell line derived from a non adherent chicken embryonic stem cells which is capable of proliferating in the absence of exogenous trophic factors and cytokines.

The Mehtali's declaration states that *"The ultimate proof of the ES status of cultured avian cells is the demonstration of the totipotency of such cells. To do so, the inventors have realized an experiment to evaluate the ability of chicken ES cells maintained during more than 2 weeks into culture to contribute to in vivo reconstruction of a chicken embryo (See Appendix N^oI). Thus the inventors demonstrate the germ-line transmission of cultured chicken ES cells according to the process of the invention."* see page 4-5 and Appendix-1).

However the declaration(s) fall short of providing any evidence that demonstrates the germ-line transmission of cultured chicken ES cells produced by the method as claimed herein. The applicant fails to establish that the cell lines (obtained via method as claimed and in the declarations submitted) are indeed the embryonic stem cells which are capable of eliciting the embryonic stem cells characteristics (*i.e. unique capacity of contributing to the morphogenesis of an embryo and of participating in germline colonization when they are re-implanted in a recipient embryo*).

At best the declarations demonstrates the making of a chicken cell line (EBx) derived from non adherent chicken embryonic stem cells which do not present any staining for EMA1 (2%) and a very light one for SSEA-1(22%) (see Mehtali's declaration page 28, Sec 5.1.2). Thus considering the state of the art and limited amount of guidance provided by the applicant is it considered highly unpredictable that one skilled in the art would be able to practice the invention as claimed without further undue amount of experimentation, which would requires phenotypic and functional characterization of any cell line obtained as an embryonic stem cell.

Furthermore, It is noted that patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable (See *Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966), *Stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."*) Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be

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provided in order to enable members of the public to understand and carry out the invention.

In instant case making a non-adherent chicken embryonic stem cell line as claimed herein is not considered routine in the art and without sufficient enabled disclosure, the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). It is noted that the unpredictability of a particular area may alone provide reasonable doubt as to the accuracy of the broad statement made in support of enablement of claims. See Ex parte Singh, 17 USPQ2d 1714 (BPAI 1991). Therefore considering the state of the art and limited amount of guidance provided in the instant specification, one skill in the art would have to engage in excessive and undue amount of experimentation to exercise the invention as claimed.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sumesh Kaushal
Primary Examiner
Art Unit 1633

/Sumesh Kaushal/
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